Docket No. TIP-0058-USPCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Paul Stoffels	Conf. No.: 7472
Appln. No.	:	10/570,228	
Filed	:	September 3, 2004	
Title	:	COMBINATION OF A PYRIMIDINE CONTAINING NNRTI WITH RT INHIBITORS	
Art Unit	:	1614	
Examiner	:	Savitha M. Rao	

I hereby certify that this correspondence is being transmitted via
The Office electronic filing system in accordance with 37 CFR 1.6(a)(4).

September 18, 2008

(Date of Transmission)

Laura A. Donnelly

(Name of applicant, assignee, or Registered Representative)

/Laura A. Donnelly/

(Signature)

September 18, 2008

(Date of Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Dear Sir:

In response to the requirement for restriction and requirement for election mailed August 19, 2008, the time for responding thereto being set to expire September 19, 2008, please consider the following remarks:

Amendments to the Claims:

The following listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A combination comprising
(i) 4-[[4-[[4-(2-cyanoethenyl)-2,6-dimethylphenyl]-amino]-2-pyrimidinyl]-amino]-benzonitrile, also named TMC278, or a stereoisomeric form thereof; or a pharmaceutically acceptable salt thereof; or a prodrug thereof; and
(ii) a nucleoside reverse transcriptase inhibitor and/or a nucleotide reverse transcriptase inhibitor; wherein TMC278 and the nucleotide reverse transcriptase inhibitor and the nucleoside reverse transcriptase inhibitor are therapeutically effective HIV inhibitors at a dose that can be administered once daily.

2. (Original) The combination according to claim 1 comprising
(i) TMC278, or a stereoisomeric form thereof; or a pharmaceutically acceptable salt thereof; or a prodrug thereof; and
(ii) a nucleoside reverse transcriptase inhibitor; wherein TMC278 and the nucleoside reverse transcriptase inhibitor are therapeutically effective HIV inhibitors at a dose that can be administered once daily.

3. (Original) The combination according to claim 1 comprising
(i) TMC278, or a stereoisomeric form thereof; or a pharmaceutically acceptable salt thereof; or a prodrug thereof; and
(ii) a nucleotide reverse transcriptase inhibitor; wherein TMC278 and the nucleotide reverse transcriptase inhibitor are therapeutically effective HIV inhibitors at a dose that can be administered once daily.

4. (Original) The combination according to claim 1 comprising
(i) TMC278, or a stereoisomeric form thereof; or a pharmaceutically acceptable salt

thereof; or a prodrug thereof; and
(ii) a nucleoside reverse transcriptase inhibitor; and
(iii) a nucleotide reverse transcriptase inhibitor; wherein TMC278 and the nucleotide reverse transcriptase inhibitor and the nucleoside reverse transcriptase inhibitor are therapeutically effective HIV inhibitors at a dose that can be administered once daily.

5. (Original) The combination according to claim 1 comprising
(i) TMC278, or a stereoisomeric form thereof; or a pharmaceutically acceptable salt thereof; or a prodrug thereof; and
(ii) a nucleoside reverse transcriptase inhibitor; and
(iii) a second nucleoside reverse transcriptase inhibitor other than the nucleoside reverse transcriptase inhibitor of (ii) ; wherein TMC278 and the nucleoside reverse transcriptase inhibitors are therapeutically effective HIV inhibitors at a dose that can be administered once daily.

6. (Previously Presented) The combination according to claim 1, wherein TMC278 occurs in its E-isomeric form.

7. (Previously Presented) The combination according to claim 1, wherein the nucleotide reverse transcriptase inhibitor and/or the nucleoside reverse transcriptase inhibitor or inhibitors select mutations in the reverse transcriptase that do not cause resistance to TMC278.

8. (Previously Presented) The combination according to claim 1 wherein the nucleotide reverse transcriptase inhibitor is tenofovir or its prodrug tenofovir disoproxil fumarate.

9. (Previously Presented) The combination according to claim 1 wherein the nucleoside reverse transcriptase inhibitor is emtricitabine, racemic FTC, lamivudine (also named 3TC), abacavir or a pharmaceutically acceptable salt thereof.

10. (Previously Presented) The combination according to claim 1 wherein the nucleoside reverse transcriptase inhibitor is emtricitabine.

11. (Previously Presented) The combination according to claim 1 wherein the combination comprises
(i) TMC278 or a pharmaceutically acceptable salt, and
(ii) tenofovir or its prodrug tenofovir disoproxil fumarate, and
(iii) emtricitabine.

12. (Previously Presented) The combination according to claim 1 wherein the nucleoside reverse transcriptase inhibitor is lamivudine.

13. (Original) The combination according to claim 8 wherein the combination comprises
(i) TMC278 or a pharmaceutically acceptable salt, and
(ii) tenofovir or its prodrug tenofovir disoproxil fumarate, and
(iii) lamivudine.

14. (Previously Presented) The combination according to claim 1 wherein the nucleoside reverse transcriptase inhibitor is abacavir or a pharmaceutically acceptable salt thereof.

15. (Original) The combination according to claim 14 wherein the combination comprises
(i) TMC278 or a pharmaceutically acceptable salt, and
(ii) tenofovir or its prodrug tenofovir disoproxil fumarate, and
(iii) abacavir or a pharmaceutically acceptable salt thereof.

16. (Previously Presented) The combination according to claim1 wherein the combination comprises
(i) TMC278 or a pharmaceutically acceptable salt, and
(ii) lamivudine, and
(iii) emtricitabine.

17. (Previously Presented) The combination according to claim 1 wherein the combination comprises
(i) TMC278 or a pharmaceutically acceptable salt, and
(ii) abacavir, or a pharmaceutically acceptable salt thereof; and
(iii) emtricitabine.

18. (Previously Presented) The combination according to claim 1 wherein the combination comprises
(i) TMC278 or a pharmaceutically acceptable salt, and
(ii) lamivudine, and
(iii) abacavir, or a pharmaceutically acceptable salt thereof.

19. (Previously Presented) The combination according to claim 1 wherein weight ratio of each couple of components of the triple combination taken on a daily basis may vary in a range from 1/4 to 4/1.

20. (Previously Presented) A product containing a combination as claimed in claim 1 as a combined preparation for simultaneous, separate or sequential use against HIV infection.

21. (Previously Presented) A pharmaceutical formulation comprising a pharmaceutically acceptable carrier and a combination as claimed in claim 1.

22. (Original) The formulation of claim 21 comprising as active ingredients (i) TMC278 or its stereoisomeric form or pharmaceutically acceptable salt or its prodrug, and (ii) a nucleoside reverse transcriptase inhibitor, and (iii) a nucleotide reverse transcriptase inhibitor.

23. (Previously Presented) A combination as claimed in claim 1 for use as a medicine.

24. (Currently Amended) ~~Use of a~~ A method of preventing HIV infection comprising administering the combination as claimed in claim 1 ~~for the manufacture of a medicament for the prevention of HIV infection or transmission via sexual intercourse or related intimate contact between partners~~.

REMARKS

I. THE OBJECTION TO CLAIM 24

The Office Action objects to claim 24 as containing non-statutory subject matter. In response, Applicants submit that the amendment to claim 24 obviates any basis for the objection thereto. Claim 24 thus falls within Groups VII-IX of the requirement for restriction. Reconsideration and withdrawal of the objection to claim 24 are respectfully requested.

II. THE REQUIREMENT FOR RESTRICTION

The Office Action requires restriction of the claims to one of the following inventions:

Group I, claims 1, 2, 5, 5, 6, 7, 9, 10, 12, 14 and 16-24, drawn to a combination and a pharmaceutical formulation comprising TMC 278 and a nucleoside reverse transcriptase inhibitor;

Group II, claims 1, 3, 6, 7, 8 and 19-24, drawn to a combination and a pharmaceutical formulation comprising TMC 278 and a nucleotide reverse transcriptase inhibitor;

Group III, claims 1, 4, 6-15 and 19-24, drawn to a combination and a pharmaceutical formulation comprising TMC 278, a nucleoside reverse transcriptase inhibitor and a nucleotide reverse transcriptase inhibitor;

Groups IV-VI, claim 24, drawn to methods of manufacturing a medicament;

Group VII, claim 24, drawn to a method of prevention of HIV infection or transmission by treatment with a nucleoside reverse transcriptase inhibitor;

Group VIII, claim 24, drawn to a method of prevention of HIV infection or transmission by treatment with a nucleotide reverse transcriptase inhibitor; and

Group IX, claim 24, drawn to a method of prevention of HIV infection or transmission by treatment with a nucleoside reverse transcriptase and a nucleotide reverse transcriptase inhibitor.

In response, Applicants elect Group II with traverse with regard to Groups III, VIII and IX. Applicants respectfully submit that a search and examination for the combination of TMC 278 with a nucleotide reverse transcriptase inhibitor would not be an undue burden as such search would lead to any disclosure with regard to what is claimed in Groups III, VIII and IX. Rejoinder of at least Groups II and III, VIII and IX are respectfully requested.

Reconsideration and withdrawal of the requirement for restriction are respectfully requested.

III. THE ELECTION OF SPECIES REQUIREMENT

The Office Action requires election of species as follows:

1. With regard to Groups I, III, IV, VI, VII and IX, a nucleoside reverse transcriptase inhibitor selected from A: emtricitabine; B: lamivudine; and C: abacavir; and

2. With regard to Groups I, IV and VII, either D: absence of nucleoside reverse transcriptase inhibitor; or E: presence of nucleoside reverse transcriptase inhibitor.

In response, although there is no election of species requirement for Group II, should the Office include Groups III, VIII and IX with Group II, Applicants elect the following:

1. A: emtricitabine; and

2. D: absence of nucleoside reverse transcriptase inhibitor.

Reconsideration and withdrawal of the election of species requirement are respectfully requested.

IV. CONCLUSION

Early consideration and prompt allowance of the claims are respectfully requested.

Respectfully submitted,

/Laura A. Donnelly/
By:_____
Laura A. Donnelly
Reg. No. 38,435

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-1729
Dated: September 18, 2008